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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,844	07/10/2003	Johann Kindlein	3560-0131P	9987

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EXAMINER	
LUSTUSKY, SARA	
ART UNIT	PAPER NUMBER
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/615,844	KINDLEIN ET AL.	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/05/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/05/06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 5 September 2006. The Examiner acknowledges the amendments to claims 1-6, 11-13, 16 and 18-22. The Examiner further acknowledges the new title, the changes to the abstract and the changes to the specification. Claims 1-22 are pending.

Priority

2. As noted in the Office Action dated 05/04/06, the applicant has not filed a certified copy of the 02077799.1 European application, now European Patent 1380319, as required by 35 U.S.C. 119(b).

Drawings

3. The drawings were received on 9/05/06. These drawings are acceptable.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. With regards to the "means for delivering...radiation energy" in claims 1, 8, 9, 10, this limitation meets the three-prong test per MPEP 2181 and thereby invokes 35 USC 112 6th paragraph.

6. Regarding claims 5 and 19, which recite a "catheter probe drive means for", claim 6 which recites "a catheter tube drive means for" and claim 10 which recites a

"wire drive means for"; the examiner does not consider these claims to invoke 35 USC 112 6th paragraph. The "catheter probe drive means", "catheter tube drive means" and the "wire drive means" are all phrases referring to elements and therefore the word "means" has been used to indicate an apparatus.

7. **Claims 1, 2, 3, 4, 6, 7, 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (U.S. Patent No. 5536240) in view of Singh (U.S. Patent No. 6599237 B1).

8. Claim 1 - Edwards at al. teaches a catheter probe (182), having an elongated body with a circumferential surface, a distal end (186) and a proximal end (182), said elongated body of said catheter probe (184) (figure 13) having a longitudinal bore extending from said distal end towards at least one outlet opening (216) (figure 6) present in said circumferential surface near said proximal end (column 7, lines 19 – 29); a catheter tube (54) (figure 4) having a distal end and a proximal sharp end (56)(figure 5)(column 7, lines 29-30), which catheter tube is to be inserted with its proximal sharp end through said longitudinal bore of said elongated body, said outlet opening and through said urethral wall towards at least one desired location within the prostate to be treated (column 20, lines 39-52). Edwards et al. teaches a catheter probe as described above but does not teach the use of a urethral probe.

9. Singh teaches a urethral probe (10) (figure 2, 2A) of sufficient size to accommodate other surgical instruments (column 2, lines 30-32). This sheath, as disclosed by Singh, "acts like an artificial protective lining for the body opening through which it is passed, e.g., the urethra" (Abstract). Furthermore, instruments including a

catheter probe "can be inserted and removed by being passed into the body through the lumen of the sheath" (Abstract) and are thus movable accommodated within the urethral probe.

10. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a urethral probe as taught by Singh with a catheter probe of Edwards et al. to allow quick and more accurate positioning of a catheter while minimizing the discomfort to the patient (Singh column 3, lines 50-51).

11. Claim 2 – The combination as described above teaches a urethral probe that allows multiple insertions, removals and manipulations of various surgical instruments (column 2, lines 6-8).

12. Claim 3 – Singh teaches a urethral probe as described above as an elongated self-supporting tube (10) with a proximal end (16) and distal end (14) and a longitudinal lumen (18) (figures 2, 2A) to be introduced transurethrally into the body of the patient (claim 6).

13. Claim 4 – Singh teaches a urethral probe as described above having an elongated tubular body (10) with a central longitudinal lumen (18) (figure 2) of sufficient size to accommodate elongated surgical devices (claim 1) (column 12, lines 66-67; column 13, line 1).

14. Claim 6 – Edwards et al. teaches a catheter tube drive means for moving said catheter tube within said catheter probe by using control tabs (192 and 194) located on the handle portion (180) of the device (figure 13)(column 13, lines 41-44).

15. Claim 7 – Edwards discloses a flexible catheter tube (54)(column 9, lines 44-45) having a sharpened end (56)(figure 4) (column 7, lines 28-30).

16. Claims 11 and 12 – the urethral probe of Singh can be either a resilient, highly flexible material or a stiffer material (column 3, lines 64-67; column 4, lines 1-2).

17. The combination of Edwards et al. and Singh as described above is obvious over claims 1, 2, 3, 4, 7, 11 and 12 and complies with the invocation of 35 USC 112 6th paragraph as it shows an equivalent "means for delivering" since it performs the same function of delivering treatment to specific tissues within a body.

18. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claim 1 above, and further in view of Shiber (U.S. Patent No. 5135531). The combination of Edwards et al. and Singh teaches a flexible catheter but does not disclose a catheter probe drive means for its placement and adjustment.

19. Claim 5 – the flexible catheter of Shiber can be advanced and rotated (column 3, lines 64-65) using a drive means (column 4, lines 40-46).

20. In views of the teachings of Shiber, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a drive means to position and reposition a catheter or tube, as described by the combination of Edwards et al. and Singh above, to reduce human error and increase the accuracy of positioning the device within the patient when compared to traditional manual methods as the drive means can be controlled by a computer or electronic device.

21. **Claims 8-10, 18 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claims 1 and 7, and further in view of Kindlein et al. (U.S. Patent 6454696 B1). The combination of Edwards et al. and Singh teaches the use of a catheter delivery device to deliver treatment to a particular location within the body but does not disclose a wire means to load the catheter delivery device and drive the treatment through the catheter into the tissue.

22. Claim 8 - Kindlein et al. (U.S. Patent 6454696 B1) teaches a delivery method comprising at least one wire (132)(figure 12) having a distal end (column 5, lines 12-14) and a proximal end; and at least one energy emitting source (claim 1) to be inserted by means of said proximal end of said wire through said catheter tube (10)(figure 1) towards said location to be treated (column 5, lines 19-21).

23. Claim 9 – the apparatus of Kindlein et al. (U.S. Patent 6454696 B1) as described above comprises a means for inserting said energy source within the catheter tube (claim 19).

24. Claim 10 – Kindlein et al. (U.S. Patent 6454696 B1) teaches a means for delivering comprising a wire drive means for moving a wire together with an energy-emitting source through a catheter (claims 1 and 20).

25. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the catheter delivery device of the combination of Edwards et al. and Singh, with a wire drive means to deliver an energy source, in view

of the teachings of Kindlein et al. (U.S. Patent 6454696 B1) to eliminate the many specialized and delicate tasks involved with performing this method manually, and to increase the accuracy in the placement of the treatment (column 1, lines 30-34).

26. Furthermore, the combination of Edwards et al. and Singh as described above does not disclose a method using a computer and treatment plan by which the delivery device is controlled.

27. Claim 18 – Kindlein et al. (U.S. Patent 6454696 B1) teaches that the location within the tissue to be treated is monitored and controlled by a computer program (column 1, lines 38-40) according to planning information delivered by imaging means (7)(figure 1)(column 2, lines 43-49).

28. Claim 19 – Kindlein et al. (U.S. Patent 6454696 B1) teaches a control means (12)(figure 1)(column 4, lines 25-30) for delivering treatment to the tissue comprising imaging means (7)(figure 1)(column 2, lines 43-49) and at least one computer planning treatment system (12a)(figure 1)(column 1, lines 38-40).

29. It would have been obvious to one having ordinary skill in the art at the time the invention was made to control the device as described above, in view of the teachings of Kindlein et al. (U.S. Patent 6454696 B1), using a computer program in combination with a treatment plan to administer treatment to a patient because it eliminates human error and increases efficiency (column 1, lines 30-34).

30. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. (U.S. Patent No. 5536240) and Jagpal (U.S. Patent No. 5257979) and further in view Webster (U.S. Patent No. 5569220).

31. Edwards at al. teaches a catheter probe (182), having an elongated body with a circumferential surface, a distal end (186) and a proximal end (182), said elongated body of said catheter probe (184) (figure 13) having a longitudinal bore extending from said distal end towards at least one outlet opening (216) (figure 6) present in said circumferential surface near said proximal end (column 7, lines 19 – 29); a catheter tube (54) (figure 4) having a distal end and a proximal sharp end (56)(figure 5)(column 7, lines 29-30), which catheter tube is to be inserted with its proximal sharp end through said longitudinal bore of said elongated body, said outlet opening and through said urethral wall towards at least one desired location within the prostate to be treated (column 20, lines 39-52). Edwards et al. teaches a catheter probe as described above but does not teach the use of a urethral probe.

32. Jagpal teaches a urethral probe (70)(figure 5)(column 12, lines 16-17) with a lumen (76) through which a catheter probe is movable accommodated within (column 10, lines 17-21).

33. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the urethral probe of Jagpal with the catheter device of Edwards et al. to allow repositioning of a catheter (column 5, lines 33-34), to reduce risk to the patient (column 12, lines 22-23). While Jagpal teaches a urethral probe through

which devices may be inserted to treat tissues within the body, it does not disclose the nature of the material from which the urethral probe is made.

34. Claim 13 – Webster (U.S. Patent No. 5569220) teaches the use of a flexible catheter with reinforced mesh (column 2, lines 7-10). Merriam-Webster Online Dictionary teaches the term "grating" to mean a partition or covering of parallel or crossed bars. Compact's Oxford Dictionary defines "mesh" as material made of a network of wire or thread. Therefore the examiner is taking the term mesh to mean a grating of a plurality of filaments.

35. It would have been obvious to one of ordinary skill in the art at the time the invention was made to reinforce the sheath of Jagpal for use with the delivery catheter of Edwards et al., as described above, with the mesh of Webster (U.S. Patent No. 5569220) to provide high torsional stiffness with increased flexibility (column 1, lines 56-58). This combination improves the control over placement of the device within the body (column 1, line 56) and provides tissue protection while increasing the ease of manipulation of devices within the lumen.

36. **Claims 14, 15, 16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al., Japgal and Webster as applied to claim 13 above, and further in view of Tiller et al. (PGPUB US 2003/0091641 A1).

37. The delivery device as taught by the combination of Edwards et al., Japgal and Webster includes a delivery catheter comprising a catheter probe, a urethral probe and

a sheath made of a grating of a plurality of filaments but does not disclose specific types of materials or coatings.

38. Tiller et al. teaches that medical devices can be made of and coated with a variety of materials, including metals, polymers and bioabsorbable materials. Medical devices, including urinary catheters, are prone to biofilm formation on their surfaces ([0181]).

39. Claim 14 - Tiller et al. teaches that medical devices can be made of polymers ([0060]) and materials considered to be bioabsorbable ([0162]).

40. Claim 15 – Tiller et al. teaches that medical devices can be made of metals ([0060]).

41. Claim 16 - Tiller et al. teaches coating of medical devices with tissue friendly coatings including polymers ([0052]).

42. Claim 17 – Tiller et al. teaches coating of medical devices with polyurethanes ([0052]).

43. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device as described by Edwards et al., Singh and Japgal in view of the teachings of Tiller et al., using metal, polymers and/or a bioabsorbable material as these are common materials used in the art as well as materials which are able to be sterilized, therefore minimizing tissue damage and lowering the risk of infection ([0003]).

44. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claim 1 above, and further in view of Bradshaw et al. (U.S. Patent No. 5139473). The device taught by the combination of Edwards et al. and Singh includes a catheter delivery device and a sheath but does not disclose the use of a computer or electronic system to deliver treatment to the patient.

45. Claim 20 – Bradshaw et al. teaches the use of a radioactive energy sources in common medical procedure using guide tubes, including catheters, and wire drive means (column 17, claim 1).

46. Claim 21 – the energy sources of Bradshaw et al. are high dose rate sources (column 1, lines 38 –47).

47. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device as described above by the combination of Edwards et al. and Singh, in view of the teachings of Bradshaw et al., to administer a treatment using a high dose rate source and to control the delivery via a computer. Bradshaw discloses that other radiation treatments have disadvantages including "long residency times and the requirement for surgical implantation and removal, the latter with its attendant trauma to adjacent normal tissue" (column 1, lines 34-36). In comparison, Bradshaw states that the "significant offsetting advantage of (using high dose rate sources as) a treatment regime is its extreme speed" taking "only a few minutes" and "the patient carries no radioactive implants within him from the treatment center" (column 1, lines 44-47). When using high dose rate sources, it "cannot

be openly handled or exposed to treatment facility doctors and personnel" and "even relatively short exposures may result in radiation burns" therefore it "must be conducted remotely" (column 1, lines 48-52). With respect to radiation treatments other than seed implantation, the method of Bradshaw is a functional equivalent because it ablates the targeted tissue while leaving the surrounding tissue in tact.

48. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Edwards et al. and Singh as applied to claim 1 above, and further in view of Hung et al. (U.S. Patent No. 6391026 B1). The device taught by the combination of Edwards et al. and Singh includes a catheter delivery device and a sheath but does not disclose the use of an antenna as an energy emitting source to emit radiowaves.

49. Claim 22 – Hung et al. teaches a method using an energy emitting source (409) including an antenna (410) (column 7, lines 9-12, lines 24-26) emitting radiowaves (column 13, lines 44-46)(figure 8c).

50. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the catheter device as described by the combination of Edwards et al. and Singh above with the radiowave emitting antenna of Hung et al. because this is a controllable method of ablating tissue within the body while leaving other tissue in tact (column 5, lines 3-6). Hung discloses that "other energy forms could also be used, such as light, ultrasound, radiation, microwave energy, heat, cold, direct current, and the like" (Abstract). Therefore the method of Hung is functionally equivalent.

Response to Arguments

51. The Examiner finds Applicant's arguments filed 9/05/06 with respect to the drawings, claim objections and 112 rejections persuasive therefore they are withdrawn. Applicant's arguments filed 9/05/06 regarding the rejections under 35 USC 103 have been fully considered but they are not persuasive.

52. In response to applicant's argument that the combination of Edwards et al. and Singh fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a urethral probe comprising a continuous circumference and an inner diameter that is greater than the outer diameter of the catheter probe) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

53. While the urethra probe of Singh et al. has a weakened line (71) that may rupture to accommodate larger instruments (as described in lines 28-31 of column 6 of Singh), the weakened line does not extend completely through the wall of the urethra probe (as seen in Figure 5) and thus the urethra probe has a continuous circumference. The slits (24A-24B) in Applicant's argument (as seen in Figures 2 and 2A) are part of the retention balloon (as described in lines 32-35 of column 4), which has a C-shaped configuration.

54. Furthermore, although the urethra probe of Singh is capable of rupturing if necessary to accommodate a larger medical instrument, the size of the urethra probe varies and may be selected to accommodate a variety of instrument sizes (as described

in lines 30-32 of column 2, lines 51-53 of column 3 and in lines 23-27 of column 4 of Singh). The apparatus of Edwards et al. was designed for insertion within the urethra of a patient in order to avoid a more traumatic surgical entry to the treatment location and thus is inherently limited in diameter. Edwards et al. teaches that the curved radius of the catheter tube (54 as seen in Figure 4 and 200 as seen in Figure 16) is less than or equal to 0.5cm and is limited by the diameter of the catheter probe (as described in lines 7-13 of column 4 and in lines 14-26 of column 14). Given the range of diameters for the apparatus of Edwards et al. and for the urethra probe of Singh, the combination of Edwards et al. and Singh meets the structural limitations of the claims.

55. In view of the above, the Applicant has failed to structurally distinguish the invention from the prior art references and therefore the rejections regarding claims 1-22 in the Office Action dated 05/04/06 are upheld.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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